

Claims

1-34. (Cancelled)

35. (New) A multi-dosage, storage stable liquid human growth hormone formulation consisting essentially of growth hormone in isotonic phosphate buffered solution, a preservative and a non-ionic surfactant, wherein isotonicity of the phosphate buffered solution is provided by a compound selected from the group consisting of a neutral salt, a monosaccharide, a disaccharide, and a sugar alcohol, wherein the formulation has a pH of 6.15 to 6.5.

36. (New) The formulation according to Claim 35, wherein no detectable crystallization is determined under a light microscope at 5x magnification.

37. (New) The formulation according to Claim 36, wherein no detectable crystallization is determined under a light microscope at 10x magnification.

38. (New) The formulation according to Claim 36, which is stored for a period of at least 1 month at a temperature of about 2°C or greater.

39. (New) The formulation according to Claim 38, wherein the storage temperature is from about 2°C to less than about 40°C.

40. (New) The formulation according to Claim 39, wherein the storage temperature is from about 2°C to about 25°C.

41. (New) The formulation according to Claim 40, wherein the storage temperature is from about 2°C to about 8°C and the storage is for a period of at least 6 months.

42. (New) The formulation according to Claim 39, wherein the storage temperature is about 15°C and the storage is for a period of 3 months.

43. (New) The formulation according to Claim 35, wherein the formulation has a pH of about 6.2.

44. (New) The formulation according to Claim 35, wherein isotonicity is provided by mannitol.

45. (New) The formulation according to Claim 35, wherein the preservative is selected from the group consisting of phenol, benzyl alcohol, meta-cresol, methyl paraben, propyl paraben, benzalkonium chloride, benzethonium chloride, and mixtures thereof.

46. (New) The formulation according to Claim 35, wherein the non-ionic surfactant is selected from the group consisting of a polysorbate, a poly(oxyethylene), poly(oxypropylene) block copolymer, and mixtures thereof.

47. (New) The formulation according to Claim 46, wherein the non-ionic surfactant is a poly(oxyethylene), poly(oxypropylene) block copolymer.

48. (New) The formulation according to Claim 35, wherein the concentration of the non-ionic surfactant is about 0.2% (w/v).

49. (New) The formulation according to Claim 35 having the following composition:

hGH	3.33mg/ml	(10 IU/ml)
NaH ₂ PO ₄ ·2H ₂ O	10mM phosphate buffer	
Na ₂ HPO ₄ ·7H ₂ O		
Mannitol	35mg/ml	(3.5% w/v)
Poly(oxyethylene), poly(oxypropylene)		
Block copolymer	2mg/ml	(0.2% w/v)
Benzyl alcohol	9mg/ml	(0.9% v/v)
Water for injection	q.s.	

pH 6.2

50. (New) A device for administering a liquid to a human subject by injection and loaded for use with a multi-dosage, storage stable liquid human growth hormone formulation consisting essentially of growth hormone in isotonic phosphate buffered solution, a preservative and a non-ionic surfactant, wherein isotonicity of the phosphate buffered solution is provided by a compound selected from the group consisting of a neutral salt, a monosaccharide, a disaccharide, and a sugar alcohol, wherein the formulation has a pH of 6.15 to 6.5.

51. (New) A device according to Claim 50 being a pen injector device.

52. (New) A kit comprising an injection device and a separate container comprising a multi-dosage, storage stable liquid human growth hormone formulation consisting essentially of growth hormone in isotonic phosphate buffered solution, a preservative and a non-ionic surfactant, wherein isotonicity of the phosphate buffered solution is provided by a compound selected from the group consisting of a neutral salt, a monosaccharide, a disaccharide, and a sugar alcohol, wherein the formulation has a pH of 6.15 to 6.5.

53. (New) The kit according to Claim 52, wherein the container is adapted to engage with the injection device such that in use the formulation in the container is in fluid connection with the outlet of the injection device.

54. (New) The kit according to Claim 53, wherein the injection device is a pen injector and the container is a cartridge.